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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,388	10/07/2005	Richard Ross	5585-71838-01	1917

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,388	ROSS ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. This application is a 371 of PCT/GB04/01572. For applications filed under 371, PCT rules for lack of unity apply.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups I-25. Claims 1-18, drawn to a cytokine polypeptide engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule, said cytokine polypeptide selected from the group consisting of growth hormone; leptin; erythropoietin; prolactin; TNF, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-9, IL-10, IL-11; the p35 subunit of IL-12, IL-13, IL-15; granulocyte colony stimulating factor (G-CSF); granulocyte macrophage colony stimulating factor (GM-CSF); ciliary neurotrophic factor (CNTF); cardiotrophin-1 (CT-1); leukemia inhibitory factor (LIF); oncostatin M (OSM); IFNα and IFNγ.

Group 26-50. Claims 34-38, drawn to a nucleic acid encoding a cytokine polypeptide engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule, said cytokine polypeptide selected from the group consisting of growth hormone; leptin; erythropoietin; prolactin; TNF, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-9, IL-10, IL-11; the p35 subunit of IL-12, IL-13, IL-15; granulocyte colony stimulating factor (G-CSF); granulocyte macrophage colony stimulating factor (GM-CSF);

ciliary neurotrophic factor (CNTF); cardiotrophin-1 (CT-1); leukemia inhibitory factor (LIF); oncostatin M (OSM); IFNα and IFNγ , a vector, a host cell, and a process for producing the polypeptide.

Group 51. Claims 1, 19-24, drawn to an antibody engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule.

Groups 52-76. Claims 25-33, drawn to an oligomeric polypeptide comprising at least two polypeptides engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule, said cytokine polypeptide selected from the group consisting of growth hormone; leptin; erythropoietin; prolactin; TNF, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-9, IL-10, IL-11; the p35 subunit of IL-12, IL-13, IL-15; granulocyte colony stimulating factor (G-CSF); granulocyte macrophage colony stimulating factor (GM-CSF); ciliary neurotrophic factor (CNTF); cardiotrophin-1 (CT-1); leukemia inhibitory factor (LIF); oncostatin M (OSM); IFNα and IFNγ , a vector, a host cell, and a process for producing the polypeptide.

Groups 77-103. Claim 39, drawn to a cell presenting the polypeptide engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule, said cytokine polypeptide selected from the group consisting of growth hormone; leptin; erythropoietin; prolactin; TNF, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-9, IL-10, IL-11; the p35 subunit of IL-12, IL-13, IL-15; granulocyte colony stimulating factor (G-CSF); granulocyte macrophage colony stimulating factor (GM-CSF); ciliary neurotrophic factor (CNTF);

cardiotrophin-1 (CT-1); leukemia inhibitory factor (LIF); oncostatin M (OSM); IFNα and IFNγ , a vector, a host cell, and a process for producing the polypeptide.

Groups 104-128. Claim 40, drawn to a method of treatment by administering the nucleic acid encoding a cytokine polypeptide engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule, said cytokine polypeptide selected from the group consisting of growth hormone; leptin; erythropoietin; prolactin; TNF, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-9, IL-10, IL-11; the p35 subunit of IL-12, IL-13, IL-15; granulocyte colony stimulating factor (G-CSF); granulocyte macrophage colony stimulating factor (GM-CSF); ciliary neurotrophic factor (CNTF); cardiotrophin-1 (CT-1); leukemia inhibitory factor (LIF); oncostatin M (OSM); IFNα and IFNγ , a vector, a host cell, and a process for producing the polypeptide.

Groups 129-153. Claim 41, drawn to a method of treatment by administering the cytokine polypeptide engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule, said cytokine polypeptide selected from the group consisting of growth hormone; leptin; erythropoietin; prolactin; TNF, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-9, IL-10, IL-11; the p35 subunit of IL-12, IL-13, IL-15; granulocyte colony stimulating factor (G-CSF); granulocyte macrophage colony stimulating factor (GM-CSF); ciliary neurotrophic factor (CNTF); cardiotrophin-1 (CT-1); leukemia inhibitory factor (LIF); oncostatin M (OSM); IFNα and IFNγ , a vector, a host cell, and a process for producing the polypeptide.

Groups 154-178. Claim 42, drawn to a method of treatment by administering the cell presenting a cytokine polypeptide engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule, said cytokine polypeptide selected from the group consisting of growth hormone; leptin; erythropoietin; prolactin; TNF, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-9, IL-10, IL-11; the p35 subunit of IL-12, IL-13, IL-15; granulocyte colony stimulating factor (G-CSF); granulocyte macrophage colony stimulating factor (GM-CSF); ciliary neurotrophic factor (CNTF); cardiotrophin-1 (CT-1); leukemia inhibitory factor (LIF); oncostatin M (OSM); IFNα and IFNγ , a vector, a host cell, and a process for producing the polypeptide.

Group 179. Claims 34-38, drawn to a nucleic acid encoding an antibody engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule.

Group 180. Claim 25-33, drawn to an oligomeric polypeptide comprising at least two antibodies engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule.

Group 181. Claim 39, drawn to a cell comprising an antibody engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule.

Group 182. Claim 40, drawn to a method of treatment of an animal comprising administering the nucleic acid encoding an antibody engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule.

Group 183. Claim 41, drawn to a method of treatment of an animal comprising administering an antibody engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule.

Group 184. Claim 42, drawn to a method of treatment of an animal comprising administering a cell presenting an antibody engineered to include a domain that directs the attachment of at least one glycosylphosphatidylinositol molecule.

NOTE: Should any one of the Groups from 1-184 be elected, Applicants are required to select one polypeptide (one cytokine) as set forth in claim 7. Once one polypeptide is selected Applicants are required to select one domain at set forth in SEQ ID NO:12, 13, or 14. If growth hormone is selected, Applicants are required to select one modification from the list of modifications set forth in claims 13-18, e.g. histidine 18 aspartic acid. Once one polypeptide modification is selected, all other modifications and sequences will be withdrawn from consideration.

NOTE: Independent claim 1 and claim 7 reads on polypeptides that are not related in structure and function, and therefore this claim is considered to comprise an improper Markush group. Claim 1 is not a proper linking claim because it, in fact, comprises multitudes of polypeptide sequences.

Applicants must choose a single polypeptide sequence for examination. This is not a species election, but an election of a single invention.

If Applicants believe that their sequences are so overlapping as to be obvious variants of each other, Applicants may choose a single sequence for search, this sequence being a representative sequence of all sequences or a designated subset of the sequences, as Applicants may choose. If Applicants present a single sequence to represent all sequences claimed, it will be understood that if this sequence or any sequence is found, the remaining sequences will be considered to be obvious variants of the found sequence.

The inventions listed as Groups I-184 do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical feature for the following reasons:

The PCT rules define a special technical feature as a feature, which defines a contribution over the prior art. The first claimed invention fails to recite such a feature, since Benting et al (1999) teach a chimeric protein in which rat growth hormone (an unglycosylated, unpolarized secreted protein) has been modified into a glycosylphosphatidylinositol-anchored protein and then analyzed its surface delivery in polarized MDCK cells (see abstract, page 313). The protein of the reference meets the limitations of the chimeric polypeptide of Group I engineered to include a domain comprising a sequence that directs the attachment of at least one glycosylphosphatidylinositol molecule.

Since the first claimed invention lacks a special technical feature, the other claimed inventions cannot share a special technical feature with the first claimed invention. The inventions of Groups 26-50 are patentably distinct from the products of Groups I-25 because the products of Groups 1-25 can be synthesized by materially different methods, such as by chemical

synthesis. Similarly, the inventions of Group 51 are patentably distinct from the product of Group 179 because the products of Group 51 can be synthesized by a materially different method, such as by chemical synthesis. The inventions of Groups I-25 and 26-50 are patentably distinct from the product of Group 51 because the product of Group 51 can be used in methods that are materially different from the methods in which the inventions of Groups 1-25, 26-50 are used, such as in immunoaffinity chromatography. Similarly, the inventions of Groups 179-181 are patentably distinct from the product of Group 51 because the product of Group 51 can be used in methods that are materially different from the methods in which the inventions of Groups 179-181 are used, such as in immunoaffinity chromatography.

The methods of Groups 104-128, 129-153, 154-178, 182, 183, 184 are patentably distinct from each other because each recites method steps not required by the other, each method uses different starting materials and the search of all methods in one patent application would result in an undue search burden.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Rejoinder under *In re Ochiai, In re Brouwer*

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the

product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1646
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